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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,986	12/12/2001	Dennis R. Burton	TSRI 313.2 C1	6775

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,986	BURTON ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *12-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 29-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/13/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-11 and 29-30 in the reply filed on 08/09/2004 is acknowledged. The restriction/election is then made Final. Claims 12-28 are withdrawn from the consideration. Claims 1-11 and 2-30 are considered before the examiner.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. The invention of claims 1-6 and 8-11 is directed to non-statutory subject matter. There is no recitation of isolation or synthesis in front of the claimed compound. Therefore, the claimed compound read on naturally occurring materials, which are considered to be non-statutory and non-patentable subject matter within the scope of 35 U.S.C. 101. See Official Gazett, 1077 O.G. April 21, 1987. It is recommended that the claim incorporate the claim language, " isolated or synthesized" to overcome this rejection.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-11 and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 is vague and indefinite for using an indefinite language "preferentially". Because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). This affects the dependent claims 2-10 and 29-30.

9. Claim 5 is vague and indefinite for recitation of " a preselected" since it is entirely unclear what criteria would constitute " the preselected" for all disclosure of the application. Claim 6 is vague and indefinite for recitation of " a second field strain". The claim is interpreted in light of the specification; however, the specification does not teach which criteria constitute the " second field strain", such as a primary isolate, secondary isolate and laboratory isolate etc. If applicants wish to claim a human monoclonal antibody that binds to a particular strain(s) of HIV, please specify the virus strain(s). Otherwise, the claims are considered indefinite.

10. Claims 9-11 are vague and indefinite for recitation of "conservative substitution thereof". The claim is interpreted in light of the specification; however, the specification does not teach what kind of amino acid substitutions would be encompassed within the metes and bounds of the claimed conservative substitutions, and specification does not have a definition or defined criteria for the recited "conservative substitutions.". The claims are considered indefinite.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-11 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

13. The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is based an analysis of many factors outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988) set forth bellow:

14. It is well known in the art that the production of monoclonal antibodies is unpredictable since there is a low probability of obtaining the same or similar monoclonal antibodies to a particular antigen. The state of art teaches that the formation of an intact antigen-binding site specificity generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity, which are characteristics of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs are required in their proper order and in the context of framework sequences for maintaining their required conformation in order to produce a same antigen-binding specificity and affinity. Even minor changes in the amino acid sequences of the heavy and light variable regions, especially the conserved region, may dramatically affect antigen-binding function as evidenced by Colman P.M (Research in Immunology 1994, Vol. 145 pp.33-36), Panka et al (Proc Natl Acad Sci USA 1988, Vol 85 3080-3084 5/88) and Rudikoff et al. (Proc. Natl. Acad. Sci. USA 1982 Vol 79 page 1979). Colman teaches that single amino acid sequence change within the interface of antibody and antigen complex are important in two biological contexts. In principle and practice, substitution in either partner can raise or lower the affinity. A very conserved

substitution may abolish binding (See page 35). Panka et al (see lines 6-11 on 1st col. of page 3083) demonstrate that a single amino acid substitution of serine for arginine results in decreased affinity. Rudikoff et al. teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function.

15. The specification of current application only teaches that the human monoclonal antibody designated b12, which neutralizes HIV and binds t gp120 preferably over gp160 (see claim 1) and has a heavy chain variable region sequence set forth SEQ IDNO: 66 or SEQ ID NO: 155. The broad scope of claims read on any human monoclonal antibody or Fab fragment thereof made by any conserved substitution of SEQ ID NO: 66 or SEQ ID NO: 155, which is able to be used for treating HIV. However, Applicants failed to establish that one skilled in the art would be able to reproduce antibodies having the properties of b12 without undue experimentation. Further, applicant has not set forth sufficient evidence to establish that one of skilled din the art would make or use the claimed antibodies as an "immunotherpeatically effective" reagent for treating HIV infection (claim 29).

16. The state of art teaches that treating or preventing HIV infection has many obstacles that have not been overcome so far. These include: 1) the extensive genomic diversity and frequent mutations , especially in the gene encoding the HIV gp120; 2) the latent infection; 3) the ability of the virus to evade immune response in the central nervous system due to the blood-brain barrier; and 4) the complexity and variation of the pathology of HIV infection in different individuals. Further, it is also well known in the art that while anti-gp120 antibody is a neutralizing antibody, this antibody is not protective antibody, and it does not save the patient from processing to its lethal conclusion. Takeda et al. teach that human neutralizing monoclonal antibodies HMAb N70-2.3a binds to HIV gp120 (See Fig. On 1954), however, it also mediated enhancement of HIV-1 infection (See Fig. 2 and 3 on page 1955). Most recently, the first such vaccine made by recombinant gp120 failed to protect homosexual men from HIV infection as disclosed by Tramont et al. (Expert Opin Emerg Drugs. 2003 May;8(1):37-

452, see third paragraph on page 41). Thus, it is clear that treatment of HIV infection is highly unpredictable and has met with very little success so far.

17. Applicants have not provides sufficient guidance to allow one skilled in the art to practice the claimed invention, such as dosage, routs as well as procedure etc., with a reasonable expectation of success and without undue experimentation.

18. The claimed invention is also rejected due to lack of deposit information about claimed human monoclonal antibodies. Applicants also reminded that apparently applicants claim several human monoclonal antibodies that are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

19. In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit. Applicant is reminded that the following and should amend the specification accordingly. The current address of the ATCC is as follows: American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209). If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1-7 and 9-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 11 of U.S. Patent No. 6,261,558B1, the conflict claims are not patentably distinct from each other because scopes of the conflict claims are overlapping.

22. Claims 1-9 and 11 of US Patent 6,261,558B1 (558B1) disclose human monoclonal antibodies that immunoreact with HIV-1 gp120 and neutralize HIV-1 infectivity in an in vitro assay by 50% of the virus infectivity titers at the concentrating 5-100 ng/ml (See claims 1-4), including the concentration of less than 10 ng/ml. The variable regions of said antibodies' heavy chains set forth with amino acid sequences selected from group consisting of 1, 2, 3, 4, 5, 6, 54, 55, 56, 57, 58, 59, 89, 90, 91 and 92 (See claims 8-12). The said antibodies are also claimed as a Fab fragments.

23. The current application, although word differently from the claims 1-7 and 9-11 in patent 558B1, it is also directed to a human monoclonal antibody that is able to

immunoreact with HIV gp120 and neutralize the HIV infectivity in vitro at a concentration of less than 700 ng/ml, less than 300 ng/ml or less than 30 ng/ml or less than 10 ng/ml. Said antibody is also has a same binding specificity of a monoclonal antibody comprising a heavy chain immunoglobulin variable region amino acid sequence shown in SEQ ID NO: 66 or SEQ ID NO: 155 or conservative substitution thereof. Said antibody is also a Fab fragment.

24. According to sequence comparison, it is noticed that the sequence of the variable region of human monoclonal antibodies in "558B, which is selected from group consisting of SEQ ID NO: 1, 2, 3, 4, 5, 6, 54, 55, 56, 57, 58, 59, 89, 90, 91 and 92, has a very high homology to the SEQ ID NO: 155 or SEQ ID NO: 66 (About more than 90% homology). Therefore, they are all variations of conserved substitutions of SEQ ID NO: 66 or SEQ ID NO: 155. Further, these antibodies all immunoreact with HIV-1 gp120 and neutralize HV-1 infectivity within the same concentration range.

25. Therefore, the claimed human monoclonal antibodies in patent 558B1 are all obvious variants of the claimed antibody of current application, which are encompassed in the same scope of claimed human monoclonal antibodies as current application.

26. Claims 29-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,395,275B1. Although the conflicting claims are not identical wordily in recitation, they are not patentably distinct from each other because scopes of the conflict claims are overlapping.

27. Claims 1 and 2 of patent "275B1" are drawn to a composition comprising a synthetic human monoclonal antibody and a pharmaceutical carrier. This antibody is capable of immunoreacting with HIV gp120 in an in vitro assay with 50% inhibiting concentration at less than 100 ng/ml. The patent of "275B1" is also directed to a kit for detecting HIV containing said antibody.

28. The conflict claims of current application is also directed to a composition comprising a human monoclonal antibody and a pharmaceutical carrier, wherein the said antibody immunoreacts with HIV gp120 and neutralizes the HIV infectivity with 50%

infection concentration at less than 700 ng/ml. The claimed invention is also directed to a kit for detecting HIV-1 comprising same.

29. Therefore the conflict claims read on structural and functional same composition comprising structurally. The broad scope of 50% inhibition dosage at less than 700 ng/ml in current application also encompasses the concentration of 100 ng/ml of patent "275B1".

30. More importantly, applicants are reminded that the patentability of an antibody depends on an antibody's specificity encompassed with its particular structures and functions, and it does not depend on a concentration of the antibody. Because a concentration of the antibody solely depends on the purity of an antibody and a virus titer of individual test. It is known in the art that different benches of a same monoclonal antibody isolated from a same hybridoma cell line vary from time to time. However, its specificity of an antibody remains the same. Therefore, it would have been obvious for a person with ordinary skill in the art to isolate an antibody from the same cell line, and prepare it in a composition with different concentration without unaccepted result.

Claim Rejections - 35 USC § 102

31. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Because the terminology of "preselected" or "second field" is also unclear in view of the state of art, the broad scope of claims are interpreted in any isolated HIV directed from field or a strain that isolated from a patient, which is later on adapted to grow in the laboratory).

32. Claims 1, 2, 5-6, 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Posner et al. (J. Immunol. June 1991, Vol. 146, pp. 4325-4332).

33. Posner et al. teach an isolated human mAb (HmAb) termed F105 that is able to bind HIV envelope protein gp120 and neutralize the HIV III B and MN strains infectivity at 170 ng/ml and 5 μg/ml, respectively (See entire document, especially pages 4328-4329).

34. For the examination purposes, the limitation of specificity of claimed antibody reads on the HIV binding specificity only, and is not limited to other antibody with the particular sequence of variable region of heavy chain SEQ ID NO: 66 or 155. Because the cited reference teaches that the isolated human monoclonal antibody binds to the same antigen HIV gp120 and has same biological activity that neutralizes the virus infectivity within the same dosage range as that of the rejected claims, the claims are anticipated by the cited reference.

35. Claims 1, 2, 5-6, 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorny et al. (Proc. Natl. Acad. Sci. USA, April 1991, Vol. 88, pp. 3138-3242).

36. Corny et al. teach four isolated IgG1 human monoclonal antibodies (mAbs) to the envelope glycoprotein, gp120, of human immunodeficiency virus (HV). They are named as 257-2D, 257-2, 268-11D, and 268-11. The antibodies bind to the V3 loop of HIV gp120 (See pages 3239-3240, especially Fig. 2). The antibodies are also able to neutralize the HIV infectivity for different isolated strains at different concentrations within the ranges of 0.3 ng/ml to 23 ng/ml as claimed drafted (See last paragraph of results on page 3240, Table 1 and Fig. 4).

37. For the examination purposes, the limitation of specificity of claimed antibody reads on the HIV binding specificity only, and is not limited to other antibody with the particular sequence of variable region of heavy chain SEQ ID NO: 66 or 155. Because the cited reference teaches that the isolated human monoclonal antibody binds to the same antigen HIV gp120 and has same biological activity that neutralizes the virus infectivity within the same dosage range as that of the rejected claims, the claims are anticipated by the cited reference.

38. Claims 1, 2, 5-6, 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Scott et al. (Proc. Natl. Acad. Sci. USA, 1990, Vol. 87, pp. 8597-8601).

39. Scott et al. teach an isolated human IgG monoclonal antibody (N701.9b) that recognizes the V3 loop of HIV gp120 of MN strain and several MN-like strains (see abstract). While the reference does not explicitly teach what the concentration for the 50% neutralizing HIV is, they teach that the antibody does neutralize four isolated HIV_{MN} strains at the end point concentrations from 0.095 to 1.0 μg/ml (see 2nd col. of page 8599), indicating that the concentration for the 50% inhibition must be within the range below 700 ng/ml.

40. For the examination purposes, the limitation of specificity of claimed antibody reads on the HIV binding specificity only, and is not limited to other antibody with the particular sequence of variable region of heavy chain SEQ ID NO: 66 or 155. Because the cited reference teaches that the isolated human monoclonal antibody binds to the same antigen HIV gp120 and has same biological activity that neutralizes the virus infectivity within the same dosage range as that of the rejected claims, the claims are anticipated by the cited reference.

41. Claims 1, 2, 5-6, 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ho et al. (J. Virol. 1991, Vol. 65, No. 1, pp. 489-493).

42. Ho et al. teach an isolated human IgG monoclonal antibody 15e that binds gp120 of all 11 HIV isolates (See page 489). they also teach that the antibody neutralizes six laboratory strains of HIV and 10 primary filed isolated HIV strains. The antibody concentrations for inhibiting 50% virus infectivity for most primary isolates are less than 100 ng/ml.

43. For the examination purposes, the limitation of specificity of claimed antibody reads on the HIV binding specificity only, and is not limited to other antibody with the particular sequence of variable region of heavy chain SEQ ID NO: 66 or 155. Because the cited reference teaches that the isolated human monoclonal antibody binds to the same antigen HIV gp120 and has same biological activity that neutralizes the virus

infectivity within the same dosage range as that of the rejected claims, the claims are anticipated by the cited reference.

44. Claims 1, 2, 5-6, 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tilley et al. (Res. Virol. 1991, Vol. 142, pp. 247-259).

45. Tilley et al. teach an isolated human IgG monoclonal antibody 1125H that binds to gp120 of to most isolated strains (See page 247). They also teach that the antibody neutralizes the infectivity of several tested viruses (See Fig. 3 on page 253). The antibody concentration for inhibiting 50% virus infectivity for HIV MN strain is less than about 700 ng/ml.

46. For the examination purposes, the limitation of specificity of claimed antibody reads on the HIV binding specificity only, and is not limited to other antibody with the particular sequence of variable region of heavy chain SEQ ID NO: 66 or 155. Because the cited reference teaches that the isolated human monoclonal antibody binds to the same antigen HIV gp120 and has same biological activity that neutralizes the virus infectivity within the same dosage range as that of the rejected claims, the claims are anticipated by the cited reference.

Claim Rejections - 35 USC § 102

47. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

48. Claims 1, 2, 5-6, 8-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Kang al. et (Proc. Natl. Acad. Sci. USA, 1992, Vol. 89, pp. 2546-2550).

49. Kang et al. teach an isolated human IgG monoclonal antibody ($3C9^+$ Ab) that binds to HIV gp120 of MN strain and HIV SF2 and IIIB strains (See 1st paragraph of RESULTS on page 2547). They also teach that the antibody is able to neutralize four primary isolated HIV strains (Fig. 1 on right of page 2548) and several laboratory strains

(Fig. 1 on left on page 2548). The concentration for the 50% neutralizing HIV infectivity is around 400 ng/m/ for primary isolated HIV strains N70 P-1 and around 700 ng/ml for primary isolated JSH P-1 strains.

50. For the examination purposes, the limitation of specificity of claimed antibody reads on the HIV binding specificity only, and is not limited to other antibody with the particular sequence of variable region of heavy chain SEQ ID NO: 66 or 155. Because the cited reference teaches that the isolated human monoclonal antibody binds to the same antigen HIV gp120 and has same biological activity that neutralizes the virus infectivity within the same dosage range as that of the rejected claims, the claims are anticipated by the cited reference.

51. Claims 1, 2, 5-6, 8-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Tilley et al. (AIDS Res. And Human Retro. 1992, Vol. 8, No. 4, pp. 461-467).

52. Tilley disclose an isolated human neutralizing monoclonal antibody against V3 loop and CD4-binding site of gp120 (4117C HuMab). The antibody binds several divergent HIV-1 strains, including MN, SF-2 and some Africa isolates. They also teach that the concentration for 50% neutralization of MN strain is about 0.7 μg/ml (See page 463).

53. For the examination purposes, the limitation of specificity of claimed antibody reads on the HIV binding specificity only, and is not limited to other antibody with the particular sequence of variable region of heavy chain SEQ ID NO: 66 or 155. Because the cited reference teaches that the isolated human monoclonal antibody binds to the same antigen HIV gp120 and has same biological activity that neutralizes the virus infectivity within the same dosage range as that of the rejected claims, the claims are anticipated by the cited reference.

54. Claims 1, 2, 5-6, 8-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Karwowska et al. (AIDS Res. And Human Retro. June 1992, Vol. 8, No. 6, pp. 1099-1106).

55. Karwowska et al. disclose several isolated human neutralizing monoclonal antibody that bind to CD4-binding site of gp120. One of them designated Mab 559/64-D neutralizes HIV- 1 II B strain at the concentration of 500 ng/ml can inhibit 50% of HIV-1 III B (See pages 1102-1103).

56. For the examination purposes, the limitation of specificity of claimed antibody reads on the HIV binding specificity only, and is not limited to other antibody with the particular sequence of variable region of heavy chain, SEQ ID NO: 66 or 155. Because the cited reference teaches that the isolated human monoclonal antibody binds to the same antigen HIV gp120 with same biological activity that neutralizes the virus infectivity within the same dosage range as that of the rejected claims, the claims are anticipated by the cited reference.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

JAMES HOUSEL 9/7/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

August 29, 2004